



Delaware Health and Social Services
Division of Public Health

DELAWARE STATE BOARD OF HEALTH
RULES AND REGULATIONS PERTAINING TO
BIRTHING CENTERS

Adopted by the State Board of Health
on October 23, 1987 and effective as of
December 1, 1987.

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Under the authority granted to the State Board of Health under 16 Delaware Code, Chapter 1, Subchapter II 122(3) (o) the Board of Health for the State of Delaware hereby adopts the following regulations pertaining to the delivery of birthing center services in the State of Delaware.

Section 53.0 - Definition

Birthing Center means any public or private health facility or institution which is not licensed as a hospital or as a part of a hospital and provides care during delivery and immediately after delivery for generally less than twenty-four hours.

Services provided in a birthing center shall be limited in the following manner: a) surgical services shall be limited to those normally performed during uncomplicated childbirth, such as episiotomy and repair, and shall not include operative obstetrics or caesarean sections; b) labor shall not be stimulated or augmented with chemical agents during first or second stage of labor; c) systemic analgesia may be administered and local anesthesia for pudendal block and episiotomy and laceration repair may be performed.

Section 53.1 - Licensing Requirements

- A. The term birthing center shall not be used as part of the name of any agency or description of services in the State unless it has been so classified by the State Board of Health.
- B. License:
 - 1. A license shall be effective for a twelve (12) month period and may be issued for that period only if the Birthing Center is in full compliance with these regulations.

2. A provisional license may be granted by the Board of Health for a period not exceeding three (3) months when the Birthing Center is in compliance with most but not all of these regulations and has demonstrated the ability and willingness to comply within the three (3) month period.
3. A license is not transferrable from person to person nor from one location to another.
4. A license shall be conspicuously posted.
5. All applications for renewal of licenses shall be filed with the State Board of Health at least thirty (30) days prior to expiration.

Section 53.2 - Governing Body

- A. Responsibility: A governing body shall provide facilities, personnel and services necessary for the welfare and safety of the patients.
- B. Duties: The Governing Body shall:
 1. adopt by-laws in accordance with legal requirements;
 2. meet regularly and maintain accurate records of such meetings;
 3. appoint a credentials committee, composed of clinical staff, which shall have the authority and responsibility for appointments and reappointments of clinical staff and ensure that only members of the clinical staff shall admit patients to the birthing center;
 4. appoint and delineate clinical privileges of practitioners based upon recommendations by the clinical staff and other appropriate indicators of physicians and certified nurse mid-wife competence;
 5. establish a formal means of liaison with the clinical staff;
 6. clinical staff must abide by the protocols of the center and be licensed;
 7. appoint committees consistent with the needs of the birthing center.
- C. Quality of Care:
 1. Conduct, with the active participation of the clinical staff, an ongoing, comprehensive self-assessment of the quality of care provided, including the medical necessity of procedures performed, the appropriateness of care, and the appropriateness of utilization. This information shall provide

a basis for the revision of facility policies and the granting of continuation of clinical privileges.

2. Require that the facility's Quality Assurance Program ensures the adequate investigation, control and prevention of infections.
3. Provide that there shall be on file in the center an agreement with an ambulance service (air or ground) for emergency transfer of patients to hospital.

Section 53.3 - Administrator

- A. Responsibility: The administrator shall be the official representative of the governing body and the chief executive officer of the birthing center. The administrator shall be delegated responsibility and authority in writing by the governing body for the management of the birthing center and shall provide liaison among the governing body, clinical staff and other departments of the birthing center.
- B. Duties: The administrator shall be responsible for the development of Birthing Center policies and procedures for employee and clinical staff use. All policies and procedures shall be reviewed and/or updated as necessary but at least annually.

Section 53.4 - Clinical Staff

- A. Organization: The birthing center shall have an organized clinical staff restricted to physicians and certified nurse mid-wives.
- B. Definition: Certified Nurse Mid-Wife (CNM) - a professional nurse licensed in the State of Delaware who is educated in the two disciplines of nursing and midwifery, who possesses evidence of certification according to the requirements of the State Board of Health.
- C. Duties: The clinical staff or a delegated committee shall:
 1. be responsible for the quality of all medical care provided patients in the facility;
 2. hold meetings regularly and maintain accurate records of such meetings;
 3. formulate, adopt and enforce by-laws, rules, regulations and policies for the proper conduct of its members;
 4. recommend staff privileges to the governing body;

5. establish formal liaison with the governing body;
6. participate actively in the quality assurance program;
7. recommend admission and procedure policies to the governing body.

D. Clinical Staff Requirements:

1. Each staff physician shall be licensed to practice medicine in the State of Delaware and provide proof of licensure number.
2. Each certified nurse mid-wife (CNM) shall be licensed as a professional nurse and provide proof of licensure number.
3. Any physician applying for privileges at the birthing center must demonstrate hospital admitting privileges for patients who develop complications.
4. Any certified nurse mid-wife applying for privileges must provide proof of a back-up agreement with a physician who will accept consultation calls and referrals from the CNM 24 hours a day. Proof of hospital admitting privileges of the back-up physicians must be submitted.
5. A physician or certified nurse mid-wife licensed in the State of Delaware shall be present at each birth and until the woman and newborn are stable postpartum. A second person in addition to the above, who is a registered nurse with adult and infant resuscitation skills, shall be present during the delivery.
6. A certified nurse mid-wife or registered nurse with adult and infant resuscitation skills shall be present at the birthing center at all times when a patient is present. Additional and sufficient personnel shall be provided when more than one woman is in active labor.

Section 53.5 - Medical Records

- A. Facilities: The center shall provide sufficient space and equipment for the processing and safe storage of records.
- B. Personnel: A person knowledgeable in the management of Medical Records shall be responsible for the proper administration and functioning of the medical records section.
- C. Security: Medical records shall be protected from loss, damage and unauthorized use.

- D. Preservation: With the exception of medical records of minors (individuals under the age of 18 years) medical records shall be preserved as original records or on microfilm for no less than five years after the most recent patient care usage, after which time records may be destroyed at the discretion of the facility.
1. Medical records of minors shall be preserved for the period of minority plus five (5) years.
 2. Facilities shall establish procedures for notification to patients to the destruction of such records.
 3. The sole responsibility for the destruction of all medical records shall be the facility involved.
- E. Content: The medical records shall contain sufficient accurate information to justify the diagnosis and warrant the treatment and end results including, but not limited to:
1. complete patient identification and a unique identification number;
 2. admission and discharge dates;
 3. chief complaint and admission diagnosis;
 4. medical history and physical examination completed prior to birth;
 5. diagnostic tests, laboratory and x-ray reports when appropriate;
 6. progress notes if appropriate;
 7. properly executed informed consent which shall be obtained prior to the onset of labor and shall include evidence of an explanation by personnel of the birth services offered and the potential risks;
 8. patient's condition on discharge, final diagnosis and instructions given patient for follow-up care of patient and child;
 9. obstetrical records shall include in addition to the requirements for medical records the following:
 - a. prenatal care record containing at least a hemoglobin or hematocrit, urine screening, prenatal blood serology, RH factor determination, rubella titre, past obstetrical history and physical examination;
 - b. record of prenatal instructions;

- c. labor and delivery record, including reasons for induction and operative procedures if any;
 - d. records of anesthesia and analgesia and medication given in the course of labor, delivery and postpartum.
- 10. Records of newborn infants shall be maintained as separate records and shall include in addition to the requirements for medical records the following information:
 - a. date and hour of birth, birth weight and length, period of gestation, sex and condition of infant on delivery (including Apgar and any resuscitative measures taken);
 - b. mother's name and method of identification;
 - c. record of ophthalmic prophylaxis;
 - d. record of administration of RH immune globulin if any;
 - e. appropriate physical examination at birth and at discharge;
 - f. genetic screening, PKU or other metabolic disorders report;
 - g. fetal monitoring record;
 - h. copy of birth certificate;
 - i. record of follow-up of mother and newborn following discharge from the center; i.e., referral to pediatrician and/or visiting nurse, home and/or office visit.
- F. Nursing Records: Standard nursing practice and procedure shall be followed in the recording of medications and treatments, including delivery and post-delivery notes. Nursing notes shall include notation of the instructions given patients pre-delivery and at the time of discharge. All recordings shall be in ink and properly signed, including name and identifying title.
- G. Entries: All orders for diagnostic procedures, treatments and medications will conform to the respective State Regulations.

Section 53.6 - Personnel

- A. Orientation: The purpose and objectives of the birthing center shall be explained to all personnel as part of an overall orientation program.

- B. Policies: There shall be appropriate written personnel policies, rules and regulations governing the conditions of employment, the management of employees and the types of functions to be performed.

Section 53.7 - Admissions

- A. Admissions: All persons admitted to a birthing center shall be under the direct care of a member of the clinical staff and agree to remain at the center not less than four hours postpartum.
- B. Disclosure Document: As a condition of acceptance for birthing center care all persons shall sign prior to the onset of labor a disclosure document which shall contain:
1. an explanation of the services available;
 2. an explanation of the services not available, including types of anesthesia;
 3. a statement of the time to and location of the nearest hospital facilities for care of mother and child;
 4. a statement of cost.
- C. Prohibitions from Birthing Center Delivery:
1. Medical limitations:
 - a. current drug or alcohol addiction;
 - b. paraplegia, quadriplegics;
 - c. hypertensives on medications;
 - d. hypertension over 140/90;
 - e. diabetes (insulin dependent);
 - f. thrombophlebitis with this pregnancy;
 - g. severe anemia (hct. Below 30 at admission);
 - h. epileptics on medication;
 - i. mental impairment that would interfere with the ability to follow directions;

j. morbid obesity (100% over ideal body weight).

2. Obstetrical Limitations:

- a. grand multiparity with other risk factors;
- b. previous birth of a baby with serious congenital anomaly of a probably repeating type that cannot be excluded through antenatal evaluation;
- c. suspected congenital anomaly;
- d. previous Caesarean delivery;
- e. preeclampsia;
- f. multiple gestation;
- g. intrauterine growth retardation or macrosomia;
- h. documented oligohydramnios or polyhydramnios;
- i. abnormal fetal surveillance studies;
- j. fetal presentation other than vertex;
- k. rising antibody titre of any type that is known to affect fetal well-being;
- l. all RH sensitizations;
- m. significant third trimester bleeding of unexplained cause;
- n. need for induction of labor (no induction allowed);
- o. need for general or conduction anesthesia;
- p. need for C-section (no C-section allowed);
- q. placental abnormalities (previa or abruptio) which might threaten the neonate;
- r. known or suspected active genital herpes at the time of admission;
- s. premature labor (before 37 weeks) or postmaturity (after 43 weeks by dates);

- t. any other condition or need which will adversely affect the health of the mother or infant during pregnancy, labor, birth, or the immediate postpartum period.

D. Conditions Requiring Intrapartum Transfer from Birthing Center to a Hospital:

1. a desire for transfer from birth center care;
2. patient inadvertently admitted with any of the listed conditions which preclude birthing center delivery;
3. excessive need for analgesia during labor, or for anesthesia other than pudendal or local;
4. failure of progressive cervical dilation or descent after trial of therapeutic steps capable of being applied at the center;
5. fetal distress without delivery imminent;
6. passage of gross meconium when delivery is not imminent;
7. development of hypertension or preclampsia;
8. intrapartum hemorrhage (placenta previa or abruptio placentae);
9. prolapsed cord;
10. change to non-vertex presentation;
11. evidence of amnionitis;
12. development of other severe medical or surgical problems.

E. Conditions Requiring for Post-Partum Transfer from Birthing Center to a Hospital:

1. Maternal:
 - a. hemorrhage not responding to treatment;
 - b. need for transfusion;
 - c. retained placenta greater than 60 minutes;
 - d. needed for extended observation that prevents discharge home;

- e. any other significant morbidity.
- 2. Infant:
 - a. Apgar less than 7 at 5 minutes;
 - b. need for oxygen beyond 5 minutes;
 - c. signs of prematurity;
 - d. signs of respiratory distress;
 - e. jaundice, anemia, polycythemia, or hypoglycemia;
 - f. persistent hypothermia (less than 97% at 2 hours of life);
 - g. persistent hypotonia;
 - h. exaggerated tremors, seizures or irritability;
 - i. any significant congenital anomaly, seen or suspected;
 - j. sign of significant birth trauma;
 - k. any other significant morbidity.

Section 53.8 - Equipment and Supplies

- A. There shall be appropriate equipment and supplies maintained for the mother and newborn to include, but not be limited to:
 - 1. a bed suitable for labor, birth and recovery;
 - 2. oxygen with flow meters and masks or equivalent;
 - 3. mechanical and/or bulb suction (immediately available);
 - 4. resuscitation equipment to include resuscitation bags, endotracheal tubes and oral airways for the mother and newborn;
 - 5. firm surfaces suitable for resuscitation;
 - 6. emergency medications, intravenous fluids and related supplies and equipment for both mother and newborn;
 - 7. fetoscope and doppler for fetal monitoring;

8. a means for monitoring and maintaining the optimum body temperature of the newborn;
9. infant scale;
10. a clock with a sweep second hand;
11. sterile suturing equipment and supplies;
12. adjustable examination light;
13. containers for soiled linen and waste materials which shall be closed or covered;
14. autoclave;
15. log book for registration of birth which shall contain at least the following:
 - a. mother's name
 - b. mother's facility number
 - c. date of delivery
 - d. time of delivery
 - e. mother's age
 - f. Gravida, Para.
 - g. newborn weight
 - h. newborn sex
 - i. gestational age
 - j. transport:
 1. mother
 2. baby
 3. where
 4. when

- 5. by whom
- k. indication for hospital delivery
- l. maternal outcome after transfer
- m. indication for newborn transfer
- n. newborn outcome after transfer
- o. death:
 - 1. neonatal
 - 2. maternal
 - 3. stillborn
- p. type of delivery
- q. condition of newborn at delivery/congenital anomalies
- r. delivery person
- s. Apgar
- t. Any required resuscitation.

Section 53.9 - Laboratory

- A. Services: Clinical pathology services shall be available as required by the needs of the patients as determined by the provider staff.
 - 1. Quality Control: Internal quality control shall be established to insure compliance with generally accepted standards of laboratory practice and procedure.

Section 53.10 - Pharmaceutical Services

- A. There shall be methods, procedures and controls which ensure the appropriation, acquisition, storage, dispensing and administration of drugs and biologicals in accordance with acceptable pharmaceutical practice and applicable state and federal laws and regulations.

- B. When the facility maintains its own pharmaceutical services, it shall comply with applicable regulations of the Delaware State Board of Pharmacy.

Section 53.11 - Housekeeping Services

- A. Organization: Each facility shall provide housekeeping services which ensure a pleasant, safe and sanitary environment. The facility shall be kept clean and orderly.
- B. Written Policies and Procedures: Appropriate written policies and procedures shall be established and followed which ensure adequate cleaning and/or disinfection of the physical plant and equipment.
- C. Storage: All cleaning materials, solutions, cleaning compounds and hazardous substances shall be properly identified and stored in a safe place.
- D. Rubbish and Refuse: All rubbish and refuse containers in treatment areas shall be impervious, lined and clean.
- E. Handwashing: All personnel shall wash their hands immediately after handling refuse.

Section 53.12 - Laundry and Linens

Written provisions shall be made for the proper handling of linens and washable goods.

- A. Outside Laundry: Laundry that is sent out shall be sent to a commercial or hospital laundry. A contract for laundry services performed by commercial laundries for birthing centers shall include these standards.
- B. Storage: If soiled linen is not processed on a daily basis, a separate, properly ventilated storage area shall be provided.
- C. Processing: The laundry processing area shall be arranged to allow for an orderly progressive flow of work from the soiled to the clean area.
- D. Washing Temperatures: The temperature of water during the washing process shall be controlled to provide a minimum temperature of 165 degrees F. for 25 minutes or 130 degrees F. if the soap/detergent supplier will verify that their products will work effectively at that lower temperature. A label indicating same shall be affixed to the laundry machine.
- E. Packaging: The linens to be returned from the outside laundry to the facility shall be completely wrapped or covered to protect against contamination.

- F. Soiled Linen Transportation: Soiled linen shall be enclosed in an impervious bag and removed from the birth room after each procedure.
- G. Soiled Linen Carts: Carts, if used to transport soiled linen, shall be constructed of impervious materials, cleaned and disinfected after each use.
- H. Clean Linen Storage: Adequate provisions shall be made for storage of clean linen.
- I. Contaminated Linens: Contaminated linens shall be afforded appropriate special treatment by the laundry.
- J. Procedures: Adequate procedures for the handling of all laundry and for the positive identifications and proper packaging and storage of sterile linens must be developed and followed.

Section 53.13 - Maintenance

- A. Written Policies and Procedures: There shall be written policies and procedures for a preventive maintenance program which is implemented to keep the entire facility and equipment in good repair and to provide for the safety, welfare and comfort of the occupants of the building(s).

Section 53.14 - Pest Control

- A. Pest Control: Adequate written policies and procedures shall be developed and implemented to provide for the effective control and eradication of insects and rodents.
- B. Outer Air Openings: All openings to the outer air shall be effectively protected against the entrance of insects and rodents, etc., by self-closing doors, closed windows, screens, controlled air currents or other effective means.

Section 53.15 - Waste Storage and Disposal

- A. Sewage and Sewer Systems: All sewage shall be discharged into a public sewer system, or if such is not available, shall be disposed of in a manner approved by the Delaware State Board of Health.

Section 53.16 - General Building

- A. The Birthing Center shall be maintained to provide a safe, clean and sanitary environment.
- B. Each birthing room shall be maintained in a condition which is adequate and appropriate to provide for the equipment, staff, supplies and emergency

procedures required for the physical and emotional care of a mother, her support person(s) and the newborn during birth, labor and the recovery period.

1. Birthing rooms shall have at least 120 square feet with minimum room dimension of 10 feet.
2. Birthing rooms shall be located to provide unimpeded, rapid access to an exit of the building which will accommodate emergency transportation vehicles and equipment.

C. Patient toilet and bathing facilities.

1. A toilet and lavatory shall be maintained in or adjacent to the vicinity of the birthing room.
2. A shower shall be available for mother's use.
3. All wall, ceiling, floor surfaces, toilets, lavatories, tubs and showers shall be kept clean and in good repair.

D. Hallways and doors providing entry/exit and access into the birthing center and birth room(s) shall be of adequate width and/or configuration to accommodate maneuvering of ambulance stretchers and wheelchairs and other emergency equipment.

E. Water Supply: There shall be an adequate supply of hot and cold running water under pressure for human consumption and other purposes which shall be in compliance with Delaware State Board of Health's Drinking Water Standards.

F. Heating and Ventilation:

1. A safe and adequate source of heat capable of maintaining a room temperature of at least 72 degrees F. shall be provided and maintained.
2. Ventilation shall remove objectionable odors, excessive heat and condensations.
3. Mechanically operated systems shall be used to supply air to and/or exhaust air from soiled workrooms or soiled holding rooms, janitor's closets, soiled storage areas, toilet rooms and from spaces which are not provided with openable windows or outside doors. All fans serving exhaust systems shall be located at the discharge end of the system.

G. Food Service:

1. When birthing center policy provides for allowing the preparation and/or storage of personal food brought in by the patient or families of patients for consumption of that family, there shall be an adequate electric or gas refrigerator and dishwashing facilities.
- H. Every bathroom door lock shall be designed to permit the opening of the locked door from the outside in an emergency.
- I. There shall be no pets on the premises.
- J. Each birthing room shall have a nurse call system.
- K. Grab bars and nurse call system shall be available in each patient bathing and toilet area.
- L. Automatic regulations of water supply temperature not to exceed 110 degrees F. at shower, bathing and handwashing facilities. Control devices shall be inaccessible to unauthorized personnel.

Section 53.17 - Fire Safety

- A. Fire Safety in Birthing Centers shall comply with the adopted rules and regulations of the State Fire Prevention Commission. Enforcement of the State Fire Regulations is the responsibility of the State Fire Prevention Commission. All applications for license or renewal of license must include, with the application, a letter certifying compliance by the Fire Marshal having jurisdiction. Notification on non-compliance with the Rules and Regulations of the State Fire Prevention Commission shall be grounds for revocation of license.
- B. Accident Prevention
 1. Emergency numbers shall be located near the telephone.
 2. There shall be a written evacuation and fire plan for the removal of patients in case of fire and other emergencies. The plan shall be posted in a conspicuous place in the building.
 3. A simulated drill shall be performed every quarter per work shift. A written record of each drill shall be kept on file.

Section 53.18 - Severability

Should any section, sentence, clause or phrase of these regulations be legally declared unconstitutional or invalid for any reason, the remainder of said regulations shall not be thereby affected.